

Sigma Diagnostics
545 South Ewing Avenue
St. Louis, MO 63103

510(k) NOTIFICATION

AMAX CS-190
Coagulation Analyzer
December 15, 1995

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ATTACHMENT 1

Summary of Safety and Effectiveness

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510(k) Summary of Safety and Effectiveness

The Amelung AMAX CS-190 Coagulation Analyzer is an automated random access multipurpose analyzer. The AMAX CS-190 Coagulation Analyzer can be used for the detection of fibrin formation utilizing either mechanical principles (ball method) or photo-optical principles to perform clot based tests such as prothrombin time(PT), activated partial thromboplastin time (APTT), fibrinogen, factor assays, and other clotting tests. In addition, the AMAX CS-190 Coagulation Analyzer can be used for chromogenic assays such as antithrombin III (AT III).

In comparison studies of clot based assays between the AMAX CS-190 Coagulation Analyzer (photo-optical or mechanical) and the TOA Medical Electronics CA-5000 (mechanical), the following regression statistics were obtained:

PT (optical)	$r = 0.989$	$y = 1.113x - 0.9$
APTT (optical)	$r = 0.907$	$y = 0.848x + 7.3$
Factor IX (optical)	$r = 0.954$	$y = 0.950x + 0.7$
Factor IX (mechanical)	$r = 0.882$	$y = 0.882x + 2.3$
Factor X (optical)	$r = 0.980$	$y = 1.019x + 0.0$
Factor X (mechanical)	$r = 0.976$	$y = 1.001x - 0.3$
Fibrinogen (optical)	$r = 0.979$	$y = 1.211x + 0.9$

In comparison studies of mechanical clot based assays between the AMAX CS-190 Coagulation Analyzer and the BBL Fibrometer, the following regression statistics were obtained:

PT	$r = 0.985$	$y = 1.067x - 0.3$
APTT	$r = 0.885$	$y = 1.427x + 0.4$

In comparison studies of chromogenic assays between the AMAX CS-190 Coagulation Analyzer and the manual spectrophotometric method, the following regression statistics were obtained:

AT III	$r = 0.848$	$y = 0.848x + 5.0$
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The coefficient of variation for precision studies was less than 4% for the PT and APTT assays, less than 9% for the factor assays, less than 10% for the fibrinogen assays, and less than 6% for AT III.

The safety and effectiveness of the AMAX CS-190 Coagulation Analyzer is demonstrated by its substantial equivalency to the predicate devices.